SKYEPHARMA PLC
Form 6-K
September 23, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a 16 OR 15d 16 OF

THE SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2003

SkyePharma PLC

(Translation of registrant s name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40F. Form 20-F x Form 40-F ¨

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes ¨ No x

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SkyePharma PLC

By: /s/ Douglas Parkhill

Name: Douglas Parkhill
Title: Company Secretary

Date: September 23, 2003

Part 1/2

FOR IMMEDIATE RELEASE **23rd SEPTEMBER 2003**

SkyePharma PLC

INTERIM FINANCIAL RESULTS

for the six months ended 30th June 2003

Financial Highlights

Turnover down £5.1 million to £22.6 million (2002: £27.7 million)
Royalty income more than quadrupled to £8.0m (2002: £1.8 million)
Operating loss £17.0 million (2002: £2.0 million)
R&D up 36% to £16.4 million (2002: £12.0 million)
Exceptional charge of £1.4 million (2002:£nil)
Deferred income up £1.2 million to £19.2 million (as of 31 December 2002: £18.0 million)
Loss per share 3.1p (2002: 0.7p)
Cash £22.0 million (as of 31 December 2002: £28.1 million)

Operating Highlights

DepoMorphine completed Phase III. NDA submitted to the FDA on 18 July and accepted in September
Paxil® CR increases market share now 40% of new US prescriptions for Paxil franchise
FDA approves Paxil® CR for additional indication (Pre-Menstrual Dysphoric Disorder)
UroXatral® approved by FDA
Propofol IDD-D completed Phase II trials
Requip® commenced Phase III trials
Pulmicort® HFA commenced Phase III trials
SkyePharma to develop an improved oral version of Altace® for King Pharmaceuticals
European rights for DepoCyte® licensed to Mundipharma in June
Brazilian rights for DepoCyte® also licensed to Pharmis

Revised Full Year Guidance

Full year revenue and profit outlook dependent on licensing agreements currently under negotiation

Ian Gowrie-Smith, SkyePharma s Executive Chairman, commented:

The company continues to increase investment in developing our expanding portfolio of proprietary drugs. Whilst some delay in concluding the out-licensing of certain of these products means higher costs now, out-licensing at a later stage of development has shown itself consistently to mean higher income later. This was exemplified in the excellent terms achieved when out-licensing DepoMorphine and Propofol IDD-D for the North American market.

Out-licensing delays also account for the potential risk to full year profitability in 2003. Whilst such an outcome is by no means certain, our belief remains that growth in royalty income will progressively reduce and maybe eliminate -our present exposure to milestone payments.

For further information, please contact:

SkyePharma PLC

Ian Gowrie-Smith Executive Chairman
Michael Ashton Chief Executive Officer
Donald Nicholson Chief Financial Officer
Peter Laing Director of Corporate Communications
Today on Tel No: 020 7466 5000 and thereafter on Tel No: 020 7491 1777

Buchanan Communications Ltd

Tim Anderson / Mark Court
Tel No: 020 7466 5000

CHAIRMAN S STATEMENT

Further progress

The first half of 2003 saw major progress, culminating in today s announcement of the FDA s acceptance of our 18 July submission of an NDA for DepoMorphine, our leading pipeline product. DepoMorphine exemplifies our business strategy of taking selected products through the development process ourselves, which we expect to increase the proportion of our future revenues derived from royalty payments. As of today, however, milestone payments are still our major source of revenues and the timing of concluding new agreements, and increased R&D investment, has meant that we are reporting a loss for the half year as the company advised might be the case earlier this year. Despite this, we are pleased to report that royalties for the half year were more than four times those for the same period last year and already exceed the level for the whole of 2002. Rising royalties are the key to the future rapid growth in earnings we expect for SkyePharma.

In April the company gave guidance that we expected revenues for the full year to grow from £70 million in 2002 to the region of £100 million. In giving that guidance, management was aware that revenues could grow to between £85 million and £115 million depending on the deal terms and timing of milestones from certain key out-licensing agreements and how much of that income was recognisable this year. Continuing negotiations could result in 2003 revenues still achieving £100 million, at which level the company would meet market earnings expectations. However, management feels it prudent to advise that revenue growth may be at the lower end of that range, with a consequent impact on the level of profitability. At the lower end of the range, the company may not achieve a full year profit in 2003.

Marketed products doing well

Our partner GlaxoSmithKline continues to be successful with Paxil® CR. Paxil® CR currently accounts for 40% of all new US Paxil® prescriptions. GlaxoSmithKline is also developing additional indications for Paxil® CR, including some for which Paxil® was never approved (such as pre-menstrual dysphoric disorder, for which FDA approval was granted in September). Despite the recent start of US generic competition for unmodified Paxil®, we remain confident that sales of Paxil® CR will continue to increase. Sales of Sanofi-Synthélabo s Xatral® OD have achieved further significant growth in Europe and other non-US markets. We are delighted that the product was approved by the FDA in June, with a US launch (as UroXatral®) expected in the autumn. We have transferred European rights for the cancer drug DepoCyte® to Mundipharma, a partner who shares our view of its potential as a treatment for lymphomatous meningitis. We expect DepoCyte® to be launched in Europe later this year.

Pipeline project momentum

An NDA for DepoMorphine, our long-acting injectable analgesic for pain relief after surgery, was submitted to the FDA on 18 July and accepted in September, joining the dry powder inhaler formulation of the asthma drug Foradil®, filed by our partner Novartis at the end of last year and currently under FDA review. Our HFA-powered, metered dose inhaler version of AstraZeneca s Pulmicort® has now moved into Phase III development, as has a new oral formulation of GlaxoSmithKline s Requip. Propofol IDD-D, an improved formulation of the sedative/anaesthetic propofol, has completed Phase II and will enter Phase III clinical trials later this year.

Both DepoMorphine and Propofol IDD-D were licensed to Endo Pharmaceuticals (Endo) for North America at the end of 2002. We expect to file DepoMorphine for European approval in the autumn.

The future

The company continues to increase investment in developing our expanding portfolio of proprietary drugs. Whilst some delay in concluding the out-licensing of certain of these products means higher costs now, out-licensing at a later stage of development has shown itself consistently to mean higher income later. This was exemplified in the excellent terms achieved when out-licensing DepoMorphine and Propofol IDD-D for the North American market.

Out-licensing delays also account for the potential risk to full year profitability in 2003. Whilst such an outcome is by no means certain, our belief remains that growth in royalty income will progressively reduce and maybe eliminate -our present exposure to milestone payments.

Ian Gowrie-Smith

Executive Chairman

REVIEW OF OPERATIONS

Despite the loss in the first half of 2003 and the possibility of a loss for the full year discussed in the Chairman s statement, we believe that we have made further encouraging progress towards our goal of sustained profitability. There were promising developments in our portfolio of marketed products and also in our new product pipeline. In addition we concluded some important new commercial agreements, with several others currently in advanced negotiations.

Products on the market

Paxil® CR is an improved formulation of GlaxoSmithKline s Paxil®, a leading SSRI antidepressant. Paxil® CR uses our Geomatrix technology to reduce gastrointestinal side-effects, an issue with all drugs of this class. Paxil® CR was launched in the USA in April 2002 and by the end of June this year accounted for 38% of all new prescriptions for the Paxil® franchise. GlaxoSmithKline reported that total US sales of Paxil® and Paxil® CR were $1.07 billion in the first half of 2003, up 9%. Paxil® CR is now marketed in the USA for treating depression and a second indication, panic disorder, and has recently been approved by the FDA for pre-menstrual dysphoric disorder. The latter indication will be unique to Paxil® CR as Paxil® had never been filed for this indication. A submission for another depression-related indication, social anxiety, is currently under review by the FDA. GlaxoSmithKline has also recently published the outcome of a study of Paxil® CR in another potential new indication, control of menopausal hot flashes (known as hot flushes in some countries).

Xatral® OD (UroXatral® in the USA), our once-daily version of Sanofi-Synthélabo s Xatral® (alfuzosin), is a treatment for the urinary symptoms of benign prostatic hypertrophy, a common condition affecting middle aged males. Xatral® OD is on the market in Europe and many other markets outside the USA. The older multidose versions of Xatral® are progressively being withdrawn from the market. Combined sales of all versions rose by 26% in the first half to 103 million. UroXatral® was approved by the FDA in June and a US launch is expected in the fourth quarter. Sanofi-Synthélabo has indicated that the launch will be fully competitive . As the older versions of Xatral®, which had to be taken two or three times a day, have never been launched in the US, UroXatral® will be a new product in the USA. Phase III trials for a second indication for Xatral® OD, acute urinary retention, are ongoing. The first filings in Europe took place in July.

DepoCyte® (known as DepoCyt® in the USA), a long-acting injectable formulation of the cancer drug cytarabine, is a treatment for lymphomatous meningitis, a serious late-stage complication of non-Hodgkin s lymphoma. During the period we reacquired European rights for DepoCyte® from Elan and licensed the product to Mundipharma for most of Europe and Eastern Europe. Mundipharma concurs with our view that the market for DepoCyte® is largely under-developed. We have also appointed Pharmis as licensee for Brazil.

Products in late-stage development

DepoMorphine is our new analgesic for post-operative pain. After completing clinical trials, we were delighted to meet our published target of filing DepoMorphine with the FDA in July. The FDA has recently formally accepted this submission, triggering a milestone payment from our partner Endo Pharmaceuticals (Endo). We expect to file with the European regulatory authorities in the autumn. DepoMorphine employs our sustained-release injectable technology so that a single epidural injection immediately before surgery maintains a therapeutically effective level of morphine for 48 hours typically the period of peak post-operative pain. There is widespread recognition that relief of post-operative pain is sub-optimal. Epidural analgesia has many theoretical advantages but is

only used in about 50% of surgical procedures today because of some practical issues. Conventional morphine is relatively short-acting so for repeat administration the epidural catheter has to be left in place, impairing patient mobility and causing complications such as infections and bleeding within the spinal column. DepoMorphine eliminates the need for an indwelling catheter and for infusion pumps.

SkyePharma has completed seven clinical trials of DepoMorphine. The Phase IIb and Phase III clinical development programme for DepoMorphine involved four separate pain models and included nearly 1000 patients. In the two pivotal trials, in hip replacement surgery and lower abdominal surgery, DepoMorphine demonstrated sustained dose-related analgesia and achieved its primary endpoint (superiority over study comparators in terms of total demand for opioid analgesics after surgery) with a high degree of statistical significance ($p<0.0001$ and $p=0.0003$ respectively). DepoMorphine also achieved statistical significance on several secondary endpoints such as patient perception of pain intensity and adequacy of pain relief. In two related Phase IIb trials, DepoMorphine was significantly better than study comparators in the caesarean section study ($p=0.0209$) and approached statistical significance in the knee arthroplasty study ($p=0.0902$). In the latter study, the primary endpoint was recalled pain intensity. DepoMorphine did achieve a high degree of statistical significance in total demand for opioid analgesics after surgery ($p=0.001$), a secondary endpoint in this trial but the primary endpoint in the three other studies. In all of these studies the safety profile of DepoMorphine was typical for an epidural opioid agent.

Having licensed DepoMorphine to Endo for North America at the end of last year, we expect to conclude a European licence by the end of this year. We are also in discussions with potential Japanese licensees.

Propofol IDD-D is our novel formulation of propofol, a widely-used injectable anaesthetic and sedative. Our formulation will not support microbial growth, a recognised problem with current versions, and should provide uninterrupted sedation for 24 hours, ideal for the fast-growing intensive care market. We have now completed Phase II trials and expect Phase III trials to start later this year. Propofol IDD-D was licensed to Endo for North America in 2002.

We are conducting clinical studies of our once-daily version of the Parkinson s disease drug Requip® (ropinirole) for GlaxoSmithKline. We commenced the Phase III trial in June, triggering a milestone payment from our partner.

Foradil® Certihaler is a new version of Novartis Foradil® (formoterol), a long-acting bronchodilator for asthma. SkyePharma developed not only the multi-dose dry-powder inhaler device but also the unique formulation of the drug. This product was filed by Novartis at the end of last year and is currently under review by the US and European regulatory agencies. We expect Foradil® Certihaler to receive approvals starting in 2004.

We are developing several other asthma drugs in metered-dose inhalers (MDIs) powered by a hydrofluoroalkane (HFA) propellant gas. We have now initiated the Phase III pivotal trial of an HFA-MDI version of AstraZeneca s inhaled steroid Pulmicort® (budesonide), also involving a milestone payment. Our own HFA-MDI version of formoterol is expected to commence Phase III trials in 2004.

We are increasingly focussing our sustained-release injectable delivery technologies on biologics protein and peptide drugs that cannot be given orally but where the current need for frequent injections is undesirable. A new formulation of human growth hormone is about to enter clinical trials.

New corporate developments

In May we announced a licence agreement with King Pharmaceuticals to develop a new oral controlled-release formulation of Altace® (ramipril), a leading angiotensin converting enzyme (ACE) inhibitor with US sales of over $500 million. This project is still at the preclinical stage. We also signed an option agreement with an undisclosed partner for an undisclosed product in the pulmonary area. In June we completed a strategic reorganisation of our research centres that culminated in a substantial reduction in staff at SkyePharma Canada, with certain activities outsourced to other sites in San Diego and Muttenz. Our partner Astralis has recently commenced the Phase I US clinical trial of its novel psoriasis treatment Psoraxine. Finally we were gratified that Micap plc, the UK yeast technology specialist in which SkyePharma has an equity stake, successfully completed an initial public offering on the AIM market in August. The value of the £2 mn investment we made in January has risen significantly.

Exciting future

The progress we have achieved this year, together with further agreements still under negotiation, makes us confident that our pipeline of new products will enable us to raise the proportion of our revenues derived from royalty payments.

Michael Ashton

Chief Executive Officer

FINANCIAL REVIEW

Turnover

In recent years the majority of our revenues have been generated in the second half of the year, and this trend is expected to continue in 2003. Revenues for the half year of £22.6 million were lower than the £27.7 million in the same period in 2002. This is primarily due to delays in the timing and recognition of milestone payments, which are still the major source of revenue in the near term. In addition some of the licensing arrangements we had anticipated concluding in the first half are now expected to be finalised in the second half. Nevertheless revenues have increased by a cumulative annual growth rate of 40% since 1996.

Contract development and licensing revenues totalled £11.4 million for the period (H1 2002: £22.7 million). Revenues recognised from milestone payments and payments received on the signing of agreements amounted to £8.6 million and included £6.0 million from three transactions; Mundipharma for the rights to market and distribute DepoCyt in most European countries, King for developing and commercialising a

modified-release formulation of Altace (Ramipril) and the signing of an option agreement in respect of an undisclosed pulmonary product. In addition SkyePharma received some £6.1 million in milestones from GlaxoSmithKline and AstraZeneca on the initiation of Phase III clinical trials of Requip (Ropinirole) and Budesonide HFA. Of this total only £1.4 million was recognised as revenue and £4.7 million deferred to match against costs in the second half and 2004.

Royalty income of £8.0 million has increased more than fourfold compared with the first half of 2002, following a similar fourfold increase achieved in the full year in 2002. In addition, royalty income for the first half of 2003 is already in excess of that for the full year in 2002. Manufacturing and distribution revenues remain unchanged at £3.2 million for the period.

Deferred income

During the period, a further net £1.2 million of turnover and other income was deferred under SkyePharma s revenue recognition policy. This results in total deferred income of £19.2 million as at 30 June 2003 comprising:

	31 December 2002	Received	Recognised	30 June 2003
	£ million	£ million	£ million	£ million
Contract development and licensing revenue	10.2	12.5	(11.4)	11.3
Other operating income	7.8	4.3	(4.2)	7.9
	18.0	16.8	(15.6)	19.2

This deferred income will be released in subsequent periods in line with the related costs or as any associated obligations under the relevant contracts are satisfied.

In addition the Group recognised £1.6 million of revenue through the statement of total recognised gains and losses rather than the profit and loss account, as the amount earned did not meet the definition of qualifying consideration.

Cost of sales

Cost of sales comprises research and development expenditures, including the costs of certain clinical trials incurred on behalf of our collaborative partners, the direct costs of contract manufacturing, direct costs of licensing arrangements and royalties payable. Cost of sales remained relatively flat in the first six months of 2003 compared with the same period last year, as costs postponed due to the delay in signing certain licensing deals were offset by increased royalty payments made to Paul Capital and the cost of reacquiring the DepoCyt European rights from Elan which the Group has expensed.

Expenses

Selling, marketing and distribution expenses increased to £2.5 million (H1 2002: £2.1 million), reflecting increased promotion and market research for both DepoMorphine and Propofol.

Amortisation of intangible assets increased by £0.4 million to £3.2 million, primarily due to the amortisation of technology acquired. Other administration expenses fell to £7.5 million in the first half, compared to £8.1 million in the first half of 2002. This reduction is primarily due to the one-off charges and professional fees incurred in the first half of 2002. The exceptional charge of £1.4 million relates to a strategic reorganisation of the Group s research centres involving a substantial reduction in staff at SkyePharma Canada.

SkyePharma s own research and development expenses in the period increased by £4.3 million to £16.4 million due mainly to increased expenditures in connection with self-funded projects, such as Propofol, DepoBupivacaine, Formoterol HFA, Human Growth Hormone and DepoMorphine in preparation for its July 2003 filing with the FDA.

Other operating income

Under the Paul Capital agreements, other operating income recognised in the first half was £4.2 million (H1 2002: £7.7 million). All of the income under the first Paul Capital agreement has now been recognised. SkyePharma received a further £4.3 million under the second Paul Capital agreement during the period which will be recognised on a cost to complete basis. During the period royalty payments of £1.3 million were expensed.

Operating results

Delays in the timing and recognition of milestone payments were the most significant factors contributing to the Group s operating loss of £17.0 million (H1 2002: £2.0 million) in the first six months of 2003. The exceptional charge incurred in connection with the reorganisation of the Group s research centres and the

increase in the Group s own research and development contributed another £5.7 million to the loss. The increase in the Group s operating loss also reflects lower levels of income received under the Paul Capital agreements. Similarly, the retained loss for the period increased to £18.7 million (H1 2002: £4.2 million), after net interest payable of £1.6 million (H1 2002: £2.0 million).

The loss per share for the period was 3.1 pence, which compares with a loss of 0.7 pence for the same period in 2002.

Foreign currency movements did not have a material impact on the results of operations in 2003 compared with 2002.

Cash balances and cash flow

At 30 June 2003 SkyePharma had cash and short-term deposits of £22.2 million and a bank overdraft of £0.3 million, compared to £28.1 million cash and no bank overdraft at 31 December 2002.

There was a net cash inflow from operating activities of £7.0 million in the first half of 2003 (H1 2002: £13.7 million). During the first half of 2003 purchases of fixed asset investments were £4.5 million including the final tranche of convertible preferred shares of Astralis Ltd, an investment in Micap plc and further purchases of SkyePharma shares as part of the Group s hedging strategy for share scheme based remuneration. The purchases of intangible fixed assets of £2.2 million relate to the access fee paid to Enzon for the PEG modification technology. The resulting cash outflow before financing for the period was £5.4 million (H1 2002: inflow £0.4 million).

Balance sheet

The balance sheet at 30 June 2003 shows shareholders funds of £109.8 million, with cumulative goodwill written off to the profit and loss account reserve of £147.6 million.

The Group has 6% Convertible Bonds due 2005 of £58.6 million. In addition, bank and other non-convertible debt amounted to £10.9 million at 30 June 2003, consisting principally of a £7.6 million property mortgage secured by the assets of Jago. Net of cash and short term deposits, this amounts to £47.3 million.

Forward looking statements

The foregoing discussions contain certain forward looking statements with respect to the Group s financial condition, results of operations and business, as well as certain development projects, collaborative partnerships and plans and objectives of SkyePharma. These statements include in particular statements regarding turnover and profit expectations, potential sales revenue from products, both currently marketed and under development, anticipated progress of clinical trials, as well as expected filing and possible launch dates for products.

By their nature forward looking statements involve risk and uncertainty that could cause actual results and developments to differ materially from those expressed or implied. The significant risks related to SkyePharma s business are discussed under the caption Risk Factors of SkyePharma s Annual Reports on Form 20-F filed with the United States Securities and Exchange Commission.

Donald Nicholson

Finance Director

Part 2/2

CONSOLIDATED PROFIT AND LOSS ACCOUNT

for the six months ended 30 June 2003

	Notes	Unaudited 6 months to 30 June 2003	Unaudited 6 months to 30 June 2002	Audited 12 months to 31 December 2002
		£ 000	£ 000	£ 000
Turnover	2	22,586	27,676	69,573
Cost of sales	2	(12,702)	(12,268)	(24,830)
Gross profit		9,884	15,408	44,743
Selling, marketing and distribution expenses		(2,518)	(2,140)	(4,769)
Administration expenses				
Amortisation		(3,226)	(2,808)	(6,506)
Other administration expenses		(7,478)	(8,072)	(13,686)
Exceptional items	4	(1,409)		
		(12,113)	(10,880)	(20,192)
Research and development expenses		(16,420)	(12,092)	(29,285)
Other operating income	3	4,173	7,660	14,219
Operating (loss)/profit		(16,994)	(2,044)	4,716
Interest receivable		512	380	1,081
Interest payable		(2,131)	(2,336)	(4,464)
(Loss)/profit on ordinary activities before taxation	2	(18,613)	(4,000)	1,333
Taxation		(76)	(165)	(224)
Retained (loss)/profit		(18,689)	(4,165)	1,109
Earnings per Ordinary Share	5			
Basic		(3.1p)	(0.7p)	0.2p
Diluted		(3.1p)	(0.7p)	0.2p

There was no material difference between the (loss)/profit on ordinary activities before taxation and the historical cost (loss)/profit before taxation in 2003 and 2002. All results represent continuing activities.

CONSOLIDATED STATEMENT OF TOTAL RECOGNISED GAINS AND LOSSES

for the six months ended 30 June 2003

	Unaudited 6 months to 30 June 2003	Unaudited 6 months to 30 June 2002	Audited 12 months to 31 December 2002
	£ 000	£ 000	£ 000
(Loss)/profit attributable to shareholders	(18,689)	(4,165)	1,109
Net currency translation effect	(37)	2,523	903
Unrealised gain on contract development	1,645		
Lapse of warrants			1,096
Total recognised gains and losses for the period	(17,081)	(1,642)	3,108

RECONCILIATION OF MOVEMENTS IN SHAREHOLDERS FUNDS

for the six months ended 30 June 2003

	Unaudited 6 months to 30 June 2003	Unaudited 6 months to 30 June 2002	Audited 12 months to 31 December 2002
	£ 000	£ 000	£ 000
Shareholders funds at the beginning of the period	124,270	95,145	95,145
Total recognised gains and losses for the period	(17,081)	(1,642)	3,108
Goodwill adjustments on deferred consideration		(188)	4,837
Equity shares issued/allocated, net of expenses		31,146	43,816
Exercise of share options, net of expenses	61	572	700
Non-equity shares converted to equity shares			(11,310)
Increase/(decrease) in shares and warrants to be issued	2,565	(5,780)	(5,780)
Revaluation of shares and warrants to be issued		188	(4,837)
Issue of warrants			311
Exercise of warrants		(37)	(624)
Lapse of warrants			(1,096)
Net movement in the period	(14,455)	24,259	29,125
Shareholders funds at the end of the period	109,815	119,404	124,270

CONSOLIDATED BALANCE SHEET

as at 30 June 2003

	Notes	Unaudited 30 June 2003	Unaudited 30 June 2002	Audited 31 December 2002
		£ 000	£ 000	£ 000
Fixed assets				
Intangible assets	6	101,572	101,453	100,015
Tangible assets		44,533	46,342	45,504
Investments	7	24,198	17,382	19,902
		170,303	165,177	165,421
Current assets				
Stock		1,156	1,342	1,256
Debtors		21,973	9,086	35,207
Investments		1,905	2,353	1,961
Cash and short-term bank deposits		22,181	51,233	28,061
		47,215	64,014	66,485
Creditors: amounts falling due within one year				
Deferred income		(17,310)	(16,073)	(15,069)
Other creditors		(18,520)	(23,730)	(19,402)
		(35,830)	(39,803)	(34,471)
Net current assets		11,385	24,211	32,014
Total assets less current liabilities		181,688	189,388	197,435
Creditors: amounts due after more than one year				
Convertible bonds due 2005		(58,584)	(58,169)	(58,377)
Deferred income		(1,843)		(2,960)
Other creditors		(10,840)	(11,636)	(11,627)
		(71,267)	(69,805)	(72,964)
Provisions for liabilities and charges	9	(606)	(179)	(201)
Net assets		109,815	119,404	124,270
Capital and reserves				
Share capital	10	62,559	62,325	62,546
Share premium		316,467	315,152	316,419
Shares and warrants to be issued	11	2,565	5,025	
Other reserves		9,311	10,683	9,311
Profit and loss account		(281,087)	(273,781)	(264,006)
Shareholders funds				
Attributable to equity interests		98,505	96,784	112,960
Attributable to non-equity interests		11,310	22,620	11,310
		109,815	119,404	124,270

CONSOLIDATED CASH FLOW STATEMENT

for the six months ended 30 June 2003

	Unaudited 6 months to 30 June 2003	Unaudited 6 months to 30 June 2002	Audited 12 months to 31 December 2002
	£ 000	£ 000	£ 000
Operating (loss)/profit	(16,994)	(2,044)	4,716
Depreciation and amortisation	6,451	5,878	12,607
Decrease/(increase) in working capital	17,518	9,824	(15,771)
Net cash inflow from operating activities	6,975	13,658	1,552
Returns on investments and servicing of finance			
Interest received	473	308	943
Interest paid	(3,752)	(3,963)	(3,913)
Interest element of finance lease payments	(15)	(65)	(130)
	(3,294)	(3,720)	(3,100)
Taxation	(5)		(224)
Capital expenditure and financial investment			
Purchase of intangible fixed assets	(2,239)	(433)	(3,035)
Purchase of tangible fixed assets	(2,385)	(2,152)	(3,238)
Purchase of fixed asset investments	(4,498)	(3,356)	(6,285)
	(9,122)	(5,941)	(12,558)
Acquisitions			
Purchase of drug delivery business of Bioglan AB		(3,595)	(3,595)
Cash (outflow)/inflow before use of liquid resources and financing	(5,446)	402	(17,925)
Management of liquid resources			
Net decrease/(increase) in amounts held on short-term bank deposit	1,734	(23,135)	(3,872)
Financing			
Issue of Ordinary Share capital	61	25,902	26,168
Issue of warrants	672		311
Debt due within one year:			
Repayment of loans		(72)	(2,992)
Debt due beyond one year:			
Repayment of loans	(137)	(139)	(929)
Capital element of finance lease payments	(550)	(458)	(937)
	46	25,233	21,621
(Decrease)/increase in cash	(3,666)	2,500	(176)

NOTES TO THE INTERIM FINANCIAL STATEMENTS

for the six months ended 30 June 2003

1 ACCOUNTING POLICIES AND THE BASIS OF PREPARATION

The interim financial statements have been prepared using accounting policies consistent with those adopted by the Group in its financial statements for the year ended 31 December 2002.

The interim report is unaudited and does not constitute statutory financial statements within the meaning of section 240 of the Companies Act 1985. The results for the period to 30 June 2003 have been formally reviewed and reported upon by the auditors on page 21 to this report. The figures for the year ended 31 December 2002 are an extract from the audited financial statements for that period which have been delivered to the Registrar of Companies and on which the auditors have issued an unqualified report which contained no statement therein under section 237(2) or section 237(3) of the Companies Act 1985.

Consolidation

The consolidated financial information includes the financial statements for the Company and its subsidiary undertakings. Intra-group sales and profits are eliminated fully on consolidation. The results of subsidiaries sold or acquired are included in the consolidated profit and loss account up to the date of their sale or from their date of acquisition respectively.

Revenue recognition

Turnover comprises contract development and licensing, royalty and manufacturing and distribution income. Contract development and licensing income represents amounts invoiced to customers for services rendered under development and licensing agreements, including milestone payments and technology access fees. Contract revenue is recognised when earned and non-refundable and to the extent that there are no future obligations pursuant to the revenue, in accordance with the contract terms. Refundable contract revenue is treated as deferred until such time as it is no longer refundable. Royalty income represents income earned as a percentage of product sales. Advance royalties received are treated as deferred income until earned, when they are recognised as income. Manufacturing and distribution revenues principally comprise contract manufacturing fees invoiced to third parties and income from product sales.

Research and development costs

Research costs are charged as an expense in the period in which they are incurred. Development costs are also recognised as an expense in the period in which they are incurred, unless all of the criteria are met for asset recognition. The major asset recognition criteria include: the ability to define clearly the product or process, demonstration of its technical feasibility and that a commercial market for it exists. Development costs recognised as an asset do not exceed the probable net amount to be recovered in marketing the product or process and they are amortised over the estimated economic life.

Intangible fixed assets

Intangible fixed assets comprise goodwill, intellectual property and capitalised development costs. Goodwill, being the difference between the fair value of the purchase consideration and the Group s share of the fair value of the net assets acquired, is capitalised and amortised over a period of 20 years or less in line with the Directors view of its useful economic life. Prior to the introduction of FRS 10; Goodwill and intangible assets, the policy adopted was to write off goodwill to reserves. As permitted by FRS 10 goodwill written off to reserves in previous years has not been reinstated on the balance sheet and adjustments to such goodwill have been taken directly to reserves. Goodwill previously written off to reserves is charged to the profit and loss account in the event of disposal of the related business.

Intellectual property comprises acquired patents, trade marks, know-how and other similarly identified rights. These are recorded at their fair value at acquisition date and are amortised in equal instalments over their estimated useful economic lives, from the date when the transfer of technology is complete. The period over which the Group expects to derive economic benefits does not exceed 20 years. Costs associated with internally developed intellectual property are generally treated as research and development costs. Development costs are recognised under the criteria stated above.

Fixed asset investments

Investments that are held for continuing use in the business are classified as fixed asset investments and recorded in the balance sheet at cost or Directors valuation, less provision for permanent diminution in value.

Impairment of fixed assets

The carrying values of fixed assets are reviewed for impairment when there is an indication that the assets may be impaired. First year impairment reviews are conducted for acquired goodwill and intangible assets. Impairment is determined by reference to the higher of net realisable value and value in use, which is measured by reference to discounted future cash flows. Any provision for impairment is charged to the profit and loss account in the year concerned.

2 SEGMENTAL ANALYSIS

The Group s operations relate wholly to one class of business, pharmaceuticals. Further analysis of turnover and loss/profit on ordinary activities before taxation by geographical area is set out below, together with an analysis of cost of sales.

	Unaudited 6 months to 30 June 2003	Unaudited 6 months to 30 June 2002	Audited 12 months to 31 December 2002
	£ 000	£ 000	£ 000
(a) Turnover			
By class of business:			
Pharmaceuticals			
Contract development and licensing			
Milestone payments	8,581	18,138	47,736
Research and development costs recharged	2,793	4,582	7,705
	11,374	22,720	55,441
Royalties receivable	8,027	1,818	6,751
Manufacturing and distribution	3,185	3,138	7,381
	22,586	27,676	69,573
By location of customer:			
North America	4,618	3,878	34,047
UK	7,103	17,050	21,000
Europe	8,222	4,913	10,333
Rest of the world	2,643	1,835	4,193
	22,586	27,676	69,573
By location of operation:			
Europe	19,019	19,611	34,449
North America	3,567	8,065	35,124
	22,586	27,676	69,573
(b) Cost of sales			
By class of business:			

Pharmaceuticals			
Contract development and licensing	(4,076)	(6,399)	(12,649)
Royalties payable	(1,737)	(666)	(1,374)
Manufacturing and distribution	(6,889)	(5,203)	(10,807)
	(12,702)	(12,268)	(24,830)
(c) (Loss)/profit on ordinary activities before taxation			
By class of business:			
Pharmaceuticals	(18,613)	(4,000)	1,333
By location of operation:			
UK	(5,198)	(4,633)	(7,695)
Europe	3,317	7,515	7,652
North America	(15,113)	(4,926)	4,759
Operating (loss)/profit	(16,994)	(2,044)	4,716
Net interest payable	(1,619)	(1,956)	(3,383)
(Loss)/profit on ordinary activities before taxation	(18,613)	(4,000)	1,333

3 OTHER OPERATING INCOME

Paul Capital Royalty Acquisition Fund provided a total of $30 million between 2000 and 2002, in return for the sale of a portion of future royalty and revenue streams from DepoMorphine, Xatral OD, Solaraze and DepoCyt. Income of £1.2 million was recognised as other operating income under this agreement on a cost to complete basis. All of the income under this agreement has now been recognised. Royalty payments of £0.4 million have been expensed during the period.

In 2002 the Group announced another transaction under which Paul Capital will pay SkyePharma a further $30 million during 2002 and 2003, in return for a portion of the potential future royalty and revenue streams from nine products from the Group s drug pipeline. Income of £3.0 million was recognised as other operating income under this agreement on a cost to complete basis. Royalty payments of £0.9 million have been expensed during the period.

4 EXCEPTIONAL ITEMS

Following a strategic reorganisation of research centres involving a substantial reduction in staff at SkyePharma Canada, with certain activities outsourced to other sites in San Diego and Muttenz, provisions of £0.7 million were established against the cost of the reorganisation (note 9; Provisions for Liabilities and Charges). In addition £0.7 million was written down against fixed assets.

5 EARNINGS PER ORDINARY SHARE

	Unaudited 6 months to 30 June 2003	Unaudited 6 months to 30 June 2002	Audited 12 months to 31 December 2002
Basic and diluted attributable (loss)/profit (£ 000)	(18,689)	(4,165)	1,109
Basic weighted average number of shares in issue (000)	609,177	566,452	577,018
Dilutive potential Ordinary Shares (000)			20,077
Diluted weighted average number of shares in issue (000)	609,177	566,452	597,095
Earnings per Ordinary Share			
Basic	(3.1p)	(0.7p)	0.2p
Diluted	(3.1p)	(0.7p)	0.2p

In the half years 2003 and 2002 there was no difference between basic and diluted earnings per Ordinary Share since all potential Ordinary Shares were anti-dilutive. In 2002 the weighted average number of Ordinary Shares in issue was adjusted to assume conversion of all dilutive potential Ordinary Shares. Shares held by the SkyePharma PLC General Employee Benefit Trust are excluded from the weighted average number of shares.

6 INTANGIBLE FIXED ASSETS

	Goodwill	Intellectual property	Development costs	Total
	£ 000	£ 000	£ 000	£ 000
Cost				
At 1 January 2003	80,017	34,560	1,778	116,355
Exchange adjustments		(335)	(24)	(359)
Additions	2,713	2,437		5,150
At 30 June 2003	82,730	36,662	1,754	121,146
Amortisation				
At 1 January 2003	9,953	5,539	848	16,340
Exchange adjustments		23	(15)	8
Charge for the period	2,004	1,112	110	3,226

At 30 June 2003	11,957	6,674	943	19,574
Net book value at 31 December 2002	70,064	29,021	930	100,015
Net book value at 30 June 2003	70,773	29,988	811	101,572

As part of the 2001 RTP acquisition, deferred consideration became payable at 30 June 2003. In July 2003 3,690,211 SkyePharma Ordinary Shares were issued to the former RTP shareholders.

During the period the Group paid Enzon £2.2 million ($3.5 million) for access to its PEG modification technology, which has been included within intellectual property.

7 FIXED ASSET INVESTMENTS

	Unlisted investments	Own shares	Total
	£ 000	£ 000	£ 000
Cost			
At 1 January 2003	18,874	1,028	19,902
Additions	3,572	925	4,497
Charge for the period		(201)	(201)
At 30 June 2003	22,446	1,752	24,198

Astralis Limited

During the period the Group acquired the final 250,000 series A convertible preferred shares of Astralis Limited, an emerging biotechnology company based in the US, for £1.6 million ($2.5 million). The total holding as at 30 June 2003 was 200,000 common shares, 20,000 warrants and 2,000,000 series A convertible preferred shares.

Micap plc

During the period the Group acquired 5,000,000 ordinary shares of Micap plc, a science based technology company, for £2 million. Micap plc was listed on the Alternative Investment Market in August 2003.

Own shares

During the period the SkyePharma PLC General Employee Benefit Trust purchased 2 million shares.

8 ANALYSIS OF NET DEBT

	At 1 January 2003	Cash flow	Non-cash changes	Exchange movements	At 30 June 2003
	£000 s	£000 s	£ 000	£000 s	£000 s
Cash at bank and in hand	7,394	(3,394)		(696)	3,304
Bank overdraft		(272)		5	(267)
Short-term bank deposits	20,667	(1,734)		(56)	18,877
	28,061	(5,400)		(747)	21,914

Debt due within one year	(1,842)		(606)	6	(2,442)
Debt due after one year	(8,123)	137	606	36	(7,344)
Convertible bonds	(58,377)		(207)		(58,584)
Finance leases	(1,320)	550	(23)	(67)	(860)
	(69,662)	687	(230)	(25)	(69,230)
Total	(41,601)	(4,713)	(230)	(772)	(47,316)

Cash at bank and in hand and short-term bank deposits are aggregated on the balance sheet.

9 PROVISIONS FOR LIABILITIES AND CHARGES

	Pension	Restructuring	Total
	£ 000	£ 000	£ 000
At 1 January 2003	201		201
Exchange adjustments	23	14	37
Charge in the period	34	670	704
Utilised		(336)	(336)
At 30 June 2003	258	348	606

Restructuring Provision

The restructuring provision relates to the reorganisation of research centres involving a substantial reduction in staff at SkyePharma Canada (note 4; Exceptional items).

10 SHARE CAPITAL

Equity share capital

	Ordinary Shares of 10p each	Nominal value
	Number	£ 000
Issued, allotted and fully paid		
At 1 January 2003	613,458,067	61,346
Exercise of share options	130,020	13
At 30 June 2003	613,588,087	61,359

Non-equity share capital

	Deferred B Shares of 10p each	Nominal value
	Number	£ 000
Authorised and issued		
At 1 January 2003 and 30 June 2003	12,000,000	1,200

11 SHARE AND WARRANTS TO BE ISSUED

	£ 000
At 1 January 2003	
Shares to be issued in respect of RTP Pharma Inc.	2,565
At 30 June 2003	2,565

As part of the 2001 RTP acquisition, deferred consideration became payable at 30 June 2003. In July 2003. 3,690,211 SkyePharma Ordinary Shares were issued to the former RTP shareholders.

END